SEP 2 2 2008

510(k) Summary of Safety and Effectiveness for the

Dimension® EXL™ NTP Flex® Reagent Cartridge (RF623)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: k082645

B. Date of Preparation: August 15, 2008

C. Proprietary and Established Names:

Dimension® EXL™ N-terminal Pro-Brain Natriuretic Peptide (NTP) Flex® Reagent Cartridge (RF623)

D. Applicant:

Siemens Healthcare Diagnostics Inc., P.O. Box 6101, Newark, DE 19714-6101

Victor M. Carrio, Senior Manager, Regulatory Affairs

Office: (302) 631-0376 Fax: (302) 631-6299

E. Regulatory Information:

1. Regulation section: 21 CFR § 862.1117 B-type natriuretic peptide test system
2. Classification: Class II
3. Product Code: NBC, Test, Natriuretic Peptide
4. Panel: Clinical Chemistry

F. Predicate Device:

The Dimension® EXL™ N-terminal Pro-Brain Natriuretic Peptide (NTP) Flex® Reagent Cartridge (RF623) is substantially equivalent to the Dimension Vista® PBNP Flex® reagent cartridge (K6423A) cleared under K080578.

G. Device Description:

The EXL NTP method is a one-step sandwich chemiluminescent immunoassay based on LOCI® technology. LOCI® reagents include two synthetic bead reagents and a biotinylated monoclonal antibody fragment which recognize an epitope located in the N-terminal part of proBNP. The first bead reagent (Sensibeads) is coated with streptavidin and contains photosensitive dye. The second bead reagent (Chemibeads) is coated with a second antibody specific for a second independent epitope on NT-proBNP and contains chemiluminescent dye. Sample is incubated with Chemibeads and biotinylated antibody to form a particle/NT-proBNP/biotinylated antibody sandwich. Sensibeads then are added and bind to the biotin to form a bead-aggregated immunocomplex. Illumination of the complex by light at 680 nm generates singlet oxygen from Sensibeads, which diffuses to the Chemibeads and triggers a chemiluminescent reaction. The resulting chemiluminescent signal is measured at 612 nm and is directly proportional to the concentration of NT-proBNP in the sample.

H. Intended Use:

The NTP method is an *in vitro* diagnostic assay for the quantitative measurement of N-terminal pro-brain natriuretic peptide (NT-proBNP) in human serum and plasma on the Dimension® EXL™ integrated chemistry system with LOCI® Module. In individuals suspected of having congestive heart failure (CHF), measurements of NT-proBNP are used as an aid in the diagnosis and assessment of severity. The test is further indicated for the risk stratification of patients with acute coronary syndrome and heart failure.

I. Substantial Equivalence Information:

The Dimension® EXL™ N-terminal Pro-Brain Natriuretic Peptide (NTP) Flex® Reagent Cartridge (RF623) and the Dimension Vista® PBNP Flex® reagent cartridge (K6423A), cleared under K080578, were compared. A comparison of the important similarities and differences between the device and the predicate is provided in the following table:

Feature	**Dimension® EXL™ NTP Flex® Reagent Cartridge (RF623)**	**Dimension Vista® PBNP Flex® reagent cartridge (K6423A)** **K080578**
Intended Use	The NTP method is an *in vitro* diagnostic assay for the quantitative measurement of N-terminal pro-brain natriuretic peptide (NT-proBNP) in human serum and plasma on the Dimension® EXL™ integrated chemistry system with LOCI® Module. In individuals suspected of having congestive heart failure	The PBNP method is an *in vitro* diagnostic assay for the quantitative measurement of N-terminal pro-brain natriuretic peptide (NT-proBNP) in human serum and plasma on the Dimension Vista® System. In individuals suspected of having congestive heart failure (CHF), measurements of NT-proBNP are

	(CHF), measurements of NT-proBNP are used as an aid in the diagnosis and assessment of severity. The test is further indicated for the risk stratification of patients with acute coronary syndrome and heart failure.	used as an aid in the diagnosis and assessment of severity. The test is further indicated for the risk stratification of patients with acute coronary syndrome and heart failure.
Device Technology (detection)	Chemiluminescent	Chemiluminescent
Measuring Range	5 - 35,000 pg/mL	5 - 35,000 pg/mL
Antibody	Monoclonal Sheep Antibody	Monoclonal Sheep Antibody
Cut-off	125 pg/mL for patients less than 75 years old and 450 pg/mL for patients 75 years and older.	125 pg/mL for patients less than 75 years old and 450 pg/mL for patients 75 years and older.
Analytical Sensitivity	≤5 pg/mL	≤5 pg/mL
Functional Sensitivity	≤30 pg/mL	≤30 pg/mL
Analytical Specificity	Natrecor® shows no significant cross reactivity, 0 or 125 pg/mL NT-PBNP; sixteen other substances show no significant cross reactivity.	Natrecor® shows no significant cross reactivity, 0 or 125 pg/mL NT-PBNP; sixteen other substances show no significant cross reactivity.
Interferences	No significant interference from: Bilirubin conjugated up to 60 mg/dL; Bilirubin unconjugated up to 60 mg/dL; Hemoglobin up to 1000 mg/dL; Triglyceride up to 3000 mg/dL	No significant interference from: Bilirubin conjugated up to 60 mg/dL; Bilirubin unconjugated up to 60 mg/dL; Hemoglobin up to 1000 mg/dL; Triglyceride up to 3000 mg/dL
Hook Effect	No effect up to 400,000 pg/mL	No effect up to 400,000 pg/mL
Calibration Interval	30 days, same reagent lot	30 days, same reagent lot
Sample Volume	8 µL	8 µL

J. Conclusion:

The Dimension® EXL™ N-terminal Pro-Brain Natriuretic Peptide (NTP) Flex® Reagent Cartridge (RF623) is substantially equivalent to the Dimension Vista® PBNP Flex® reagent cartridge (K6423A) cleared under K080578. Comparative testing performed by Siemens Healthcare Diagnostics Inc. demonstrates substantial equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 22 2008

Siemens Healthcare Diagnostics, Inc.
c/o Victor Carrio
Senior Manager of Regulatory Affairs
P.O. Box 6101, Mail Stop 514
Newark, DE 19714-6101

Re: k082645
Trade Name: Dimension® EXL™ LOCI® N-terminal Pro-Brain Natriuretic Peptide (NTP) Flex® Reagent Cartridge (RF623)
Regulation Number: 21 CFR 862.1117
Regulation Name: B-type Natriuretic Peptide Test System
Regulatory Class: Class II
Product Codes: NBC
Dated: September 10, 2008
Received: September 11, 2008

Dear Mr. Carrio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known):

Device Name:

Dimension® EXL™ LOCI® N-terminal Pro-Brain Natriuretic Peptide Flex® reagent cartridge (RF623)

Indications for Use:

The NTP method is an *in vitro* diagnostic assay for the quantitative measurement of N-terminal pro-brain natriuretic peptide (NT-proBNP) in human serum and plasma on the Dimension® EXL™ integrated chemistry system with LOCI® Module. In individuals suspected of having congestive heart failure (CHF), measurements of NT-proBNP are used as an aid in the diagnosis and assessment of severity. The test is further indicated for the risk stratification of patients with acute coronary syndrome and heart failure.

Prescription Use __X__ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K082645